FDA Update

Office of In Vitro Diagnostics and Radiological Health (OIR)

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Outline

- MCM and NGS
- CARB
- PMAs
- *De novos*
- CLIA Waivers
- Meetings
- Guidances

Medical Countermeasures Initiative

- 2010- FDA launches MCMi: to identify and resolve regulatory challenges to MCM development- (drug/vaccine/device/diagnostics)
- 2013- PAHPRA: new legal authorities for FDA to support preparedness and response efforts
- Emergency Use Authorization (EUA): Rapid interactive FDA review process- 1st=2009 H1N1

MCM Diagnostic 510(k)s -2014-15

- CDC PCR *B. anthracis* detection cleared
- Pandemic Influenza : 3 new and 14 modifications to existing tests cleared
- Several bio-threat diagnostic assays, single and multiplex in the pipeline
- Monthly discussions held with CDC (LRN) and DoD

EUAs - 2014-2015

- H7N9 Avian Influenza- 2 assays authorized
- MERS-CoV-asymptomatic contacts added to intended use. Stakeholder Workshop 4/15
- Ebola Zaire - 9 diagnostic assays (commercial & non-commercial –CDC/DoD) authorized – “presumptive detection of ebola nucleic acid or antigen”. WHO/FDA collaborative reviews
- Enterovirus D68- emergency declared 3/15

High Throughput Next Generation Sequencing (NGS) Devices for Microbes

- **Infectious Disease NGS Dx**

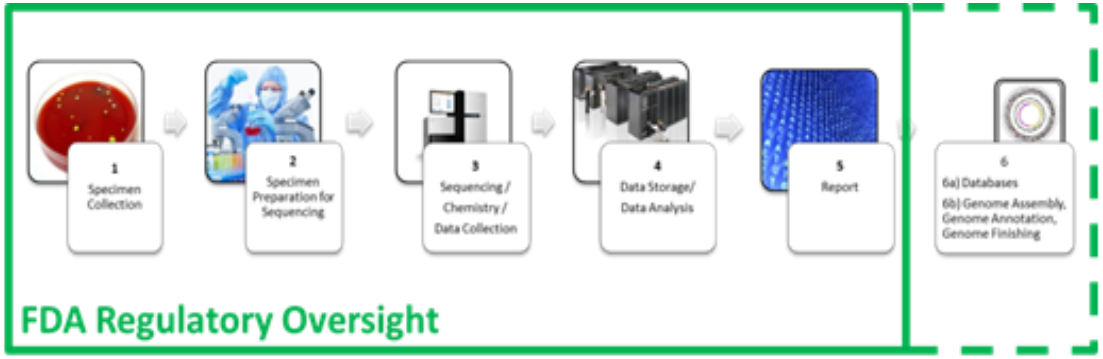
  Very different from human NGS:

  - Absolute need for immediate and actionable result
  - Broad range of specimen types
  - Large diversity of infectious disease agents present in one specimen
  - Dynamic nature of infectious disease agents

High Throughput Next Generation Sequencing (NGS) Devices for Microbes

FDA Public Workshop held 4/14 Outcomes:

- Need FDA Regulatory-Grade Microbial Database
- Clinical applications and public health needs discussed
- Device validation: Developed and specified standards for the microbial genome sequencing process
- Reference databases: Developed quality criteria for reference databases and database itself (FDA-ARGOS collaboration).
- NIST/FDA collaboration producing sequence based reference material
- Streamlined clinical evaluations/trials for microbial identification



National Action Plan for Combating Antibiotic- Resistant Bacteria (CARB)

- Streamline regulatory processes for updating (breakpoints) and clearing new AST devices
- CDC/FDA developing well characterized, publically available microbial resistance strain panel for anti-microbial resistance Dx and Tx developers
- Develop and maintain sequence data base of resistant pathogens (ARGOS collaboration)

PMA Approvals IVDs

- QIAGEN's artus® CMV RGQ MDx Kit
  - aid in the management of solid organ transplant patients who are undergoing anti-CMV therapy
- Myriad's artus® BRACAnalysis CDx™
  - aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with Lynparza™ (olaparib)

De novos

- Dexcom's STUDIO on the Cloud Data Management Software
  - for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical CGM data to support effective diabetes management.

De novos

- KRONUS Zinc Transporter 8 Autoantibody (ZnT8Ab) ELISA Assay
  - aid in the diagnosis of Type 1 diabetes mellitus
- Astute Medical's NEPHROCHECK® Test System
  - aid in the risk assessment for moderate or severe acute kidney injury

De novos

- T2 Biosystems' T2Candida Panel
  - for the direct detection of Candida species from patients with symptoms of invasive fungal infections
- Dexcom Share Direct Secondary Displays
  - to notify another person, the Follower, of the patient's Dexcom G4 PLATINUM Continuous Glucose Monitoring System sensor glucose information

De novos

- Gastric Emptying Breath Test (GEBT)
  - for use in the measurement of the rate of gastric emptying of solids and as an aid in the diagnosis of delayed gastric emptying in adults who are symptomatic for gastroparesis
- EnLite™ Neonatal TREC Kit
  - an aid in screening newborns for severe combined immunodeficiency disorder (SCID)

De novos

- 23andMe Personal Genome Service Carrier Screening Test for Bloom Syndrome

CLIA Waivers by Application

- Chembio's DPP HIV 1/2 Assay
- Alere Determine HIV-1/2 Ag/Ab Combo
- Alere's i Influenza A & B
- QUIDEL's Sofia Strep A+ FIA
- diagnostic direct's Syphillis Health Check

Notable Meetings

- Regulatory Science Considerations for Software Used in Diabetes Management, November 13, 2014
- Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), January 8-9, 2015
- Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests Public Workshop, February 20, 2015
- Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies, March 24, 2015

Final Guidances

- Molecular Diagnostic Instruments with Combined Functions
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Final Guidances

- Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions
- Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

Draft Guidances

- Radiation Biodosimetry Devices
- Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices
- Procedures for Meetings of the Medical Devices Advisory Committee

Thanks